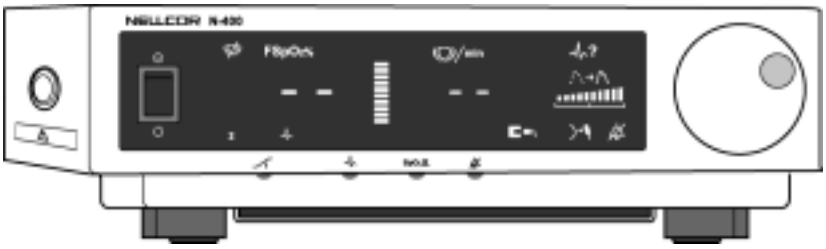
NELLCOR

OxiFirst®

Fetal Pulse Oximetry System
N-400 Operator's Manual



Use this manual with software version 4.6

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Warnings, Precautions, and System Information

Carefully read this manual, the *Information for Prescribers*, the *Clinical Use Guide*, accessory directions for use, and all warnings, precautions, and specifications before application and use of the *OxiFirst* System.

Intended Use/ Indications

The *OxiFirst* Fetal Pulse Oximetry System continuously monitors intrapartum fetal oxygen saturation (FSpO2). Use of the *OxiFirst* System is indicated **as an adjunct** to fetal heart rate monitoring in the presence of a nonreassuring fetal heart rate pattern.

The *OxiFirst* System should only be used after amniotic membranes have ruptured, and on a singleton fetus in vertex presentation with a gestational age greater than or equal to 36 weeks.

Contra-indications

Use of the *OxiFirst* Fetal Pulse Oximetry System is **contraindicated** in patients with one or more of the following conditions:

- documented or suspected placenta previa
- ominous fetal heart rate (FHR) pattern requiring immediate intervention
- need for immediate delivery (unrelated to FHR pattern), such as active uterine bleeding

Warnings

Warnings in this manual are identified by the WARNING symbol shown above.

A warning alerts you to potentially serious outcomes (death, injury, or adverse events) to the user or the patient.

WARNING: The *OxiFirst* System is intended *as an adjunct* to fetal heart rate monitoring in fetuses with a nonreassuring heart rate pattern. The *OxiFirst* System must be used in conjunction with clinical signs and symptoms.

WARNING: Locate the monitor near the patient in a position that ensures it cannot accidentally fall on the patient. Failure to do so could result in patient injury.

WARNING: The *OxiFirst* System should not be used while using an Electrosurgical Unit (ESU). Remove the fetal oximetry sensor from the mother and fetus before using an ESU. An improperly grounded ESU can cause surface skin burns on the fetus if both the *OxiFirst* System and an ESU are used together.

WARNING: The *OxiFirst* System should not be used in the presence of flammable anesthetics. Such use may constitute a fire or explosion hazard.

WARNING: The *OxiFirst* System should not be used to monitor patients during water births, in whirlpool or submersion water baths, during showers, or in any other situation where the mother is immersed in water. Doing so may result in electrical shock hazard.

WARNING: Do not use the N-400 monitor or fetal oximetry sensor during magnetic resonance imaging (MRI) scanning. Induced current may potentially cause burns or erroneous FSpO2 measurements.

WARNING: The *OxiFirst* System should not be used in women with active genital herpes or other infection precluding internal monitoring. Insertion of the fetal oximetry sensor in these women may result in transmission of pathogens to the fetus.

WARNING: The *OxiFirst* System should not be used in women who are seropositive for human immunodeficiency virus (HIV). Insertion of the fetal oximetry sensor in these patients may result in fetal exposure to the virus.

WARNING: Intrauterine insertion of the fetal oximetry sensor in women who are seropositive for Hepatitis B and/or Hepatitis E antigens may result in fetal exposure to these antigens.

Precautions

Precautions are identified by the CAUTION symbol shown above.

A caution alerts you to exercise care necessary for the safe and effective use of the *OxiFirst* system.

Clinical Use Precautions

Caution: Physicians and other licensed practitioners who use the *OxiFirst* System should have demonstrated expertise in determining fetal presentation and head position, and should be proficient in the placement of fetal scalp electrodes and intrauterine pressure catheters.

Caution: Do not attempt to insert the sensor if the patient is dilated less than 2 cm or if the amniotic membranes have not completely ruptured. Doing so may result in erroneous FSpO2 measurements and/or patient injury.

Caution: Do not attempt to rupture amniotic membranes with the sensor. Doing so may result in patient injury and/or sensor malfunction.

Caution: In situations where an FSpO2 value is not present, and efforts to readjust the sensor fail to restore the displayed value, clinical management should be based on available data, e.g. FHR. No inferences regarding fetal status should be made on the basis of earlier FSpO2 values.

Caution: Do not leave the fetal oximetry sensor in place during vacuum extraction, forceps delivery or cesarean delivery. Doing so may result in patient injury. Remove the fetal oximetry sensor before commencing any form of operative delivery.

Caution: Application of the Nellcor® Fetal Oximetry Sensor may cause temporary skin indentations, markings, or bruising on the fetus at the sensor site.

Caution: If the fetal heart rate slows during vaginal exam or sensor insertion, stop the procedure. Do not proceed with sensor placement as this can cause a reflex bradycardia stimulus. Wait for the fetal heart rate to return to the previous range before proceeding.

Technical Precautions

Caution: Suboptimal sensor placement, excessive vernix, fetal hair or motion artifact due to uterine contractions or maternal position changes may result in no FSpO2 values being displayed, or erroneous FSpO2 measurements.

Caution: The fetal oximetry sensor may be left in place during defibrillation but FSpO2 readings may be inaccurate for a short time.

Caution: Do not attempt to use any sensor other than a sterile, single-use Nellcor Fetal Oximetry Sensor with the *OxiFirst* System. Use of any other Nellcor oximetry sensor or any sensor from another manufacturer may result in system malfunction, erroneous FSpO2 readings, and/or patient injury.

Caution: When placing the Nellcor Fetal Oximetry Sensor, exercise caution to avoid interference with other internal probes, such as an intrauterine pressure catheter or a fetal scalp electrode.

Caution: Do not use a damaged sensor. Doing so may result in patient injury, sensor malfunction, and/or erroneous FSpO2 measurements.

Caution: Do not use the N-400 monitor if the outside monitor cover, or front or rear panels appear to be damaged. Doing so may result in patient injury, instrument malfunction, and/or erroneous FSpO2 measurements.

Caution: Never attempt to clean, reprocess, resterilize, or reuse fetal oximetry sensors. Doing so may result in sensor malfunction, erroneous FSpO2 measurements, and/or infection or potential tissue injury to mother and/or fetus. Each fetal oximetry sensor is supplied as a sterile, single-use, disposable device.

Caution: Do not remove the outside monitor cover. Doing so may result in electrical shock hazard. There are no user-serviceable parts inside.

Caution: Replace instrument fuses only with those of the same type and rating to protect against fire hazard.

Caution: Do not immerse the sensor completely in liquid—the connector is not waterproof. Immersion of the sensor plug in liquid may result in sensor malfunction and/or erroneous FSpO2 measurements.

Caution: Do not immerse the Fetal Patient Module completely in liquid– the unit is not waterproof. Fluid damage to the module may result in malfunction and/or erroneous FSpO2 measurements.

Caution: Do not reinsert the stylet into the sensor stylet chamber after it has been completely removed from the chamber. Doing so may result in maternal injury. Most sensor adjustments can be accomplished without the stylet being reinserted into the sensor.

Caution Do not connect Nellcor sensor extension cables, such as the EC-4 or EC-8, to the *OxiFirst* System. Unreliable readings may result due to excessive electrical interference.

Caution: For optimal clarity of audible indications and alarms, ensure that the speaker is clear of any obstruction.

Alarms

The default state of the audio alarms is OFF. If audio alarms are to be used, they must first be enabled. If audio alarms are enabled, do not set the alarm volume too low to be heard.

When the audio alarm off indicator is illuminated, no audio alarm sounds.

Inaccurate Measurements

Inaccurate measurements may be caused by:

- incorrect application or use of a sensor
- significant levels of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin
- excessive fetal or maternal patient movement
- venous pulsation

Note: The user must independently verify that the N-400 pulse rate displayed is the actual fetal heart rate. This can be done by auscultation or by comparison to an independent FHR monitoring device.

Loss-of-Pulse Signal

Loss-of-pulse signal can occur:

- during uterine contractions
- if the fetus experiences shock, hypotension, severe vasoconstriction, severe anemia, arterial occlusion proximal to the sensor, or cardiac arrest

N-400 and Other Equipment

Turn the N-400 rear-panel AC mains switch OFF before connecting data recording equipment to the N-400 monitor. To ensure patient electrical isolation, connect the N-400 only to other equipment with circuits that are electrically isolated.

When connecting the N-400 to accessory equipment, verify proper operation before clinical use. Refer to accessory equipment manual for full instructions on its use. Accessory equipment connected to the N-400's analog and digital outputs must be certified according to the respective IEC standards, that is, IEC 950 for data-processing equipment or IEC 601.1 for electromedical equipment. This equipment must be provided with either an additional protective earth conductor or a medical isolation transformer. The accessory equipment must be powered by separate wall outlets to avoid possible summation of earth leakage currents. If in doubt, consult Nellcor’s Technical Service Department or your local representative.

Electro-magnetic Interference

This device has been tested and found to comply with the limits for medical devices to the IEC 601-1-2:1993, EN60601-1-2; 1994, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in the health-care environment (for example, cellular phones, mobile two-way radios, televisions), it is possible that high levels of such interference, due to close proximity or strength of a source, may result in disruption of performance of this device.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity. Disruption or interference may be evidenced by erratic readings, cessation of operation, or incorrect functioning. If this occurs, the site of use should be surveyed to determine the source of this disruption, and actions taken to eliminate the source.

The user is encouraged to try to correct the interference by one or more of the following measures:

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reorient or relocate the other receiving device.
- Increase the separation between the interfering equipment and this equipment.
- If assistance is required, contact Nellcor's Technical Service Department.

Environ-mental Protection

Nellcor recommends that the institution follow local governing ordinances and recycling instructions regarding disposal or recycling of device components. Fetal oximetry sensors cannot be recycled.

Front Panel

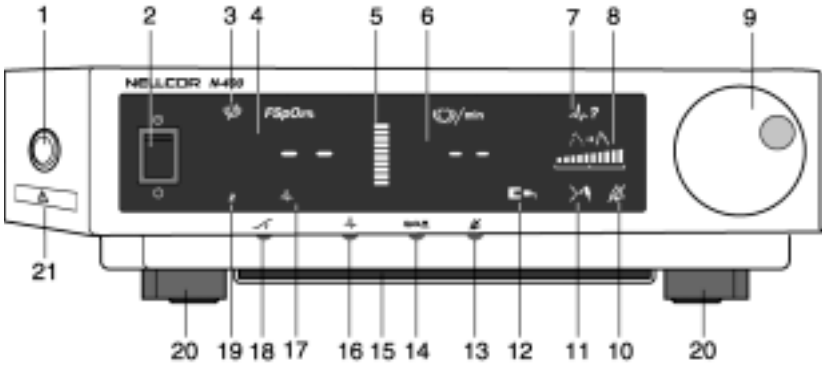


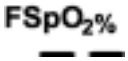
Figure 1: Front Panel

1	Fetal Patient Module connector	12	Sensor Unplugged indicator
2	On/Standby switch	13	Audio alarm off button
3	Searching indicator	14	Low Saturation Alarm limit button
4	FSpO2 display	15	Pull-out card slot
5	Pulse Amplitude indicator	16	No function
6	Pulse Rate (bpm) display	17	No function
7	No function	18	Response Time button
8	Signal quality indicator	19	Mode 2 Response Time indicator
9	Control knob	20	Adjustable feet
10	Audio Alarm Off indicator	21	Attention symbol
11	Sensor lifted indicator		

Description of Front Panel

ON/STANDBY switch: Used to turn the N-400 ON and OFF.

Searching indicator: Indicator lights when the N-400 is attempting to locate the fetal pulse.

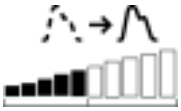


Percent Oxygen Saturation (FSpO2) display: Displays fetal oxygen saturation (FSpO2) level calculated from accepted optical pulses.

Pulse amplitude indicator: The number of bars lit indicates the relative strength of the pulse at the sensor site.

Pulse Rate display: Displays fetal pulse rate calculated from accepted pulses, measured in beats per minute (bpm).

Indicator: Feature not available at this time.



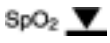
Signal Quality indicator: Indicates average signal quality of pulses being detected at the sensor site.

Control knob: Adjusts the speaker volume when audible tones or alarms sound, and is used in conjunction with push buttons to set various limits and values.

Audio Alarm Off button and indicator: Button used to silence or enable the audio alarms. Indicator lights when the audio alarm has been silenced.

Sensor Lifted indicator: Lights or flashes when sensor is not making adequate contact with the fetus at the sensor site.

Sensor Unplugged indicator: Lights when sensor is disconnected from patient module or patient module cable is disconnected from N-400.



Low Saturation Alarm Limit button: Used in conjunction with the control knob to set the low saturation alarm limit.

Button and indicator: Feature not available at this time.

Response Time button: Sets signal averaging time for FSpO2, changing from Mode 1 (default) to Mode 2 operation.

- Mode 1 (default), slow, approximately 50 seconds (at 150 bpm)
- Mode 2, fast, approximately 11 seconds (at 150 bpm)

Mode 2 rESPONSE tIME indicator: Lights when Mode 2 response time is selected.

Attention symbol: Directs user to see instructions for use or consult accompanying documents.

Rear Panel

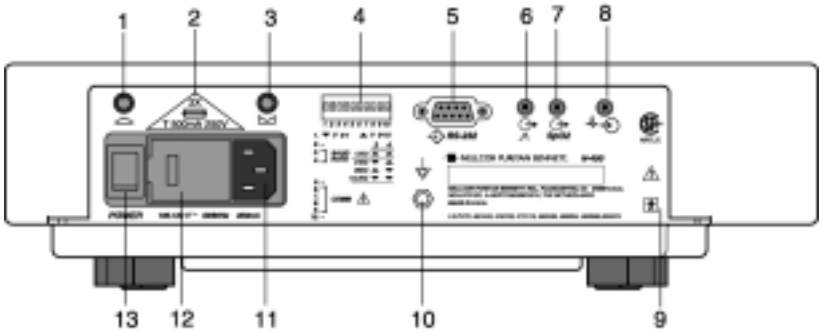


Figure 2: Rear Panel

1	Increase (full-scale) button	8	Analog input jack (not used)
2	Fuse replacement symbol	9	Type BF (patient electrically isolated)
3	Decrease (zero) button	10	Equipotential ground
4	DIP switches	11	Mains (AC) power input
5	Serial communications port (RS-232)	12	Mains (AC) voltage selector and fuse holder
6	Analog Output jack (not used)	13	Mains (AC) On/Off switch
7	FSpO2 analog output jack		

Description of Rear Panel

Increase (full-scale) button: Generates full-scale signal at analog output. Voltage is dependent upon voltage scale switch setting. (See DIP switches below.)

Fuse Replacement Symbol: Indicates fuse requirements.

Decrease (zero) button: Generates zero-voltage signal at analog output.

DIP switches:

1: Sets analog output voltage scale (DOWN = 0 - 1 V; UP = 0 - 10 V)

2, 5, 9, 10: Not used

3, 4: Sets baud rate for RS-232 output

6, 7, 8: Sets RS-232 communications format

Serial Communications Port: Provides RS-232 format digital interface via a standard 9-pin “D” connector pinout.

Analog Output jack: Feature not available at this time.

FSpO2 Analog Output jack (3/32-inch subminiature): Provides analog output of FSpO2 data with a range of 0 - 100%. Voltage is dependent upon voltage scale switch setting. (See DIP switches above.)

Analog input jack: Feature not available at this time.

Type BF: Patient electrically isolated.

Equipotential Ground: Provides an earth ground connection for leakage testing.

Mains (AC) Power Input: Connects N-400 to 100/120V~ or 220/240V~ via appropriate power cord.

Mains (AC) Voltage Selector: Allows selection of the voltage (115 or 230 VAC)

Mains (AC) ON/OFF switch: Mains (AC) power switch.

Fetal Patient Module

The Fetal Patient Module amplifies the fetal oximetry signal. The patient module has a connector for the sensor and a cable that connects to the front panel of the N-400 or to an electronic fetal heart rate monitor that uses Nellcor FSpO2 technology.

Figure 3: Fetal Patient Module

Nellcor Fetal Oximetry Sensor

Become familiar with the sensor before using it. Figure 4 shows the Nellcor Fetal Oximetry Sensor, along with descriptive labels. For additional information regarding sensor use, refer to the *OxiFirst System Clinical Use Guide*.

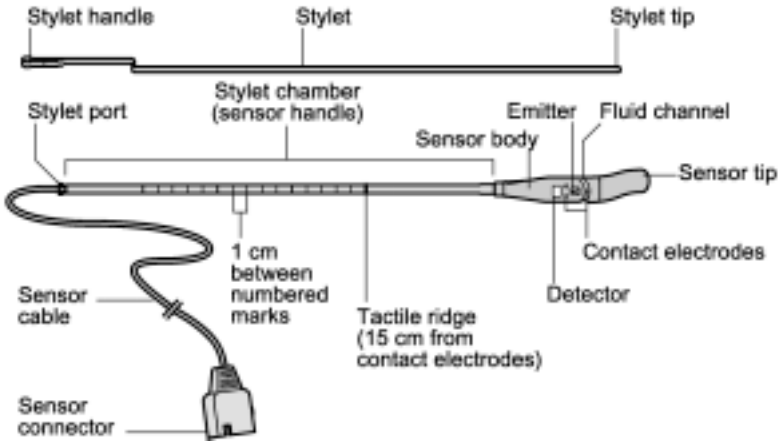


Figure 4: Nellcor Fetal Oximetry Sensor

The sensor is a sterile, single-use sensor that must not be reused. If the sensor is intentionally or accidentally removed from the patient, apply a new, sterile fetal oximetry sensor. Do not attempt to sterilize any sensor after it has been used on a patient.

Note: The sensor may be left in place during normal, unassisted vaginal delivery.

Caution: Do not leave the fetal oximetry sensor in place during vacuum extraction, forceps delivery or cesarean delivery. Doing so may result in patient injury. Remove the fetal oximetry sensor before commencing any form of operative delivery.

Overview

The *OxiFirst* Fetal Pulse Oximetry System continuously monitors intrapartum fetal oxygen saturation (FSpO2). Use of the *OxiFirst* System is indicated as an adjunct to fetal heart rate (FHR) monitoring in vertex presentation, singleton fetuses ≥ 36 weeks gestation with a nonreassuring FHR pattern as defined in the *Sensor Placement Criteria* chapter located in the *OxiFirst Clinical Use Guide*.

The OxiFirst System consists of three components:

- N-400 Fetal Pulse Oximeter,
- Fetal Patient Module
- Nellcor Fetal Oximetry Sensor

Automatic Self-test And Start-up

The N-400 provides immediate use after power-up. No operator calibration is required. During startup, the instrument performs the following internal checks:

- automatic self-test and display of error message(s) if a failure is detected
- automatic oximetry calibration
- lighting of all front panel indicators
- sounding of speaker
- display of software version number

Operator-Selectable Features

The N-400 has certain user-configurable features that may enhance the use of the system. These features include:

- Audible pulse tone for accepted pulses: Each accepted pulse produces a beep tone. The volume of the beep tone can be adjusted by the user. (Default state of this feature is ON.)
- User-configured low saturation alarm limit: Visible and audible alarm if limit is exceeded. Default alarm limit is zero.
- Two FSpO2 response-time modes that change the measurement-averaging time to suit varied clinical applications.
- Analog output of FSpO2: User selectable voltage range. Selectable zero and full scale analog output to set analog output range of recording device.
- User-configured digital output: Output includes date and time, FSpO2, pulse rate, signal quality, and monitor status.
- Audible alarms (default state is OFF), with adjustable alarm volume.

Audible Alarms

When audible alarms are enabled, and the N-400 has been displaying saturation values, any of the following conditions will cause an alarm to sound. Each of these conditions results in the loss of displayed saturation values on the N-400. An alarm will sound during the following conditions.

- FSpO2 signal is lost for 15 seconds
- sensor contact with the fetus is lost for 15 seconds
- fetal oximetry sensor is unplugged from the Fetal Patient Monitor
- Fetal Patient Module is disconnected from the N-400 Monitor
- fetal pulses of inadequate quality have been present for a sustained period of time

In addition, when the audible alarms and the low saturation alarm limit are enabled, an audible alarm will sound when the displayed FSpO2 falls below the user-selected limit.

Hemoglobin and Oxygen Transport

A review of the unique properties of hemoglobin and its role in blood oxygen transport are important in explaining how the N-400 measures fetal oxygen saturation ($FSpO_2$).

Hemoglobin, contained in red blood cells, is a complex protein molecule consisting of four iron-containing heme groups and the protein, globin; each molecule can reversibly bind four molecules of oxygen. Once one molecule of oxygen is bound, the other three follow rapidly.

A saturated hemoglobin molecule is commonly called oxyhemoglobin. Those hemoglobin molecules without oxygen are referred to as deoxyhemoglobin.

Oxygen bound to hemoglobin represents approximately 98% of the oxygen in blood, thus virtually all of the oxygen in the blood is bound to hemoglobin. The hemoglobin molecules saturated by oxygen are reflected in the saturation values of laboratory-analyzed blood gases (SaO_2) and pulse oximeters (SpO_2).

SaO_2 refers to the arterial oxygen saturation as measured by arterial blood sampling. SpO_2 refers to the arterial oxygen saturation as measured by pulse oximetry.

The N-400 reports the $FSpO_2$ value, which refers to *fetal* arterial oxygen saturation, as measured by pulse oximetry.

Principles of Pulse Oximetry and N-400 Operation

Operation of the *OxiFirst* Fetal Pulse Oximetry System is based on the principles of pulse oximetry, which in turn is based on spectrophotometry and plethysmography. The system includes an electro-optical sensor and a microprocessor-based monitor.

Oxyhemoglobin and deoxyhemoglobin have different light absorption characteristics in the red and infrared wavelength spectrums. *Less red light is absorbed by oxyhemoglobin* than by deoxyhemoglobin. *Relatively more infrared light is absorbed by oxyhemoglobin* than by deoxyhemoglobin.

The N-400 uses these differences in the absorption of red and infrared light by oxy- and deoxyhemoglobin to determine fetal oxygen saturation by measuring the change in light levels caused by pulsating arterial blood in the tissue.

The fetal oximetry sensor has two low-voltage light-emitting diodes (LEDs). One of these LEDs emits red light (nominal 735 nm wavelength) and the other emits infrared light (nominal 890 nm wavelength). When the sensor has been properly positioned on the fetal cheek, light from each of these LEDs is alternately sent through the fetal skin into the underlying tissues at the sensor site. The amount of light absorbed by the tissue or blood underlying the fetal oximetry sensor is determined from the amount of light that scatters back to the tissue surface and is picked up by the photo detector (photo diode) on the sensor.

Light absorption is first measured by the N-400 at each wavelength when no pulsatile blood is present. This reflects the background light absorption of bone, tissue, and venous blood, which are generally considered non-pulsating. This measurement is analogous to the reference measurement of a spectrophotometer.

With each fetal heart beat, a pulse of arterial blood flows to the oxygen sensor site. Red and infrared light absorption are then measured by the N-400 at each wavelength when this pulsatile, arterial blood is in the tissue. The N-400 microprocessor compares the background light absorption measurements to the absorption measured at both light wavelengths during each arterial pulse. The ratio of the corrected absorption at each wavelength is used to determine fetal oxygen saturation ($FSpO_2$).

Automatic Calibration

The N-400 oximetry subsystem is automatically calibrated each time the monitor is turned on, at periodic intervals thereafter, and whenever a new sensor is connected.

Each fetal oximetry sensor is calibrated when manufactured: the effective mean wavelength of the LEDs is determined and encoded into a calibration resistor in the sensor. The N-400 software reads this calibration resistor when the sensor is connected to determine the appropriate calibration coefficients for the measurements obtained by that specific sensor.

Functional Versus Fractional Saturation

Because the N-400 measures functional SaO_2, it may produce measurements that differ from those of instruments that measure fractional SaO_2. Functional SaO_2 is oxygenated hemoglobin expressed as a percentage of the hemoglobin that is capable of transporting oxygen. Because the N-400 uses two wavelengths, it measures oxygenated and deoxygenated hemoglobin, yielding functional SaO_2. It does not detect dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin.

In contrast, some laboratory instruments such as the Instrumentation Laboratory 282 or 482 CO-Oximeter report fractional SaO_2-oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, whether or not that hemoglobin is available for oxygen transport. Measured dysfunctional hemoglobins are included.

Consequently, to compare N-400 measurements directly with those of another instrument, that other instrument must measure functional SaO_2. If the other instrument measures fractional SaO_2, those measurements can be converted to functional SaO_2 using the following equation:

$$\text{functional saturation} = \frac{\text{functional saturation}}{100 - (\%\ \text{carboxyhemoglobin} + \%\text{methemoglobin})} \times 100$$

Measured Versus Calculated Saturation

When SaO_2 is calculated from a blood gas measurement of the partial pressure of arterial oxygen (PaO_2), the calculated value may differ from the N-400 $FSpO_2$ measurement. This is because the calculated SaO_2 may not have been corrected for the effects of variables that shift the relationship between PO_2 and SO_2 (see Figure 5): temperature, pH, the partial pressure of carbon dioxide (PCO_2), and the concentrations of 2,3-DPG and fetal hemoglobin.

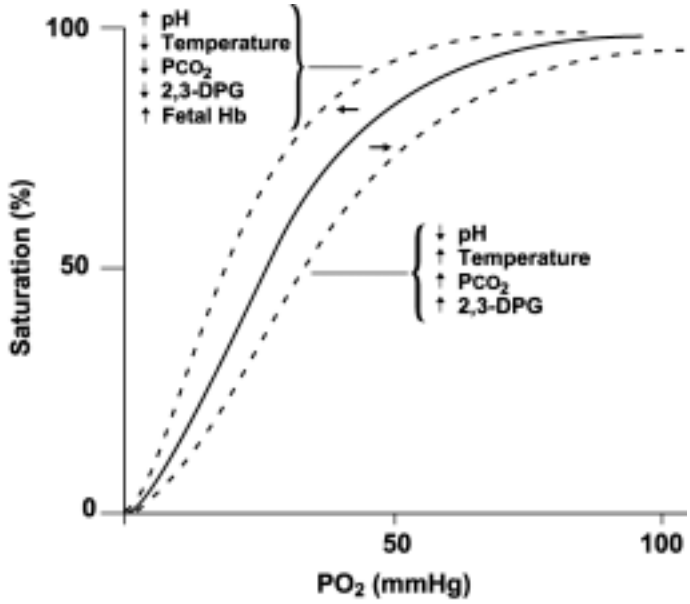


Figure 5: Oxyhemoglobin Dissociation Curve

FHR and Optical Pulse Rate Determination

The *OxiFirst* System measures fetal pulse rate in a different way than an electronic fetal heart rate monitor (EFM) measures fetal heart rate.

Fetal Heart Rate Measurement

Electronic fetal heart rate monitors determine fetal heart rate either by ultrasound or electrocardiography. An ultrasound transducer placed on the maternal abdomen directs an ultrasonic beam toward the fetal heart. This transducer detects the Doppler shifted frequency variations in the echoes created by moving cardiac structures. An autocorrelation process is used to resolve the time interval between successive cardiac cycles, producing the displayed fetal heart rate. When a spiral electrode is attached directly to the fetal presenting part, the fetal heart rate is computed based upon the time interval between successive R-wave peaks of the fetal QRS complex.

Optical Pulse Rate Determination

By measuring the optical response of light that passes through arterial blood, the *OxiFirst* System identifies fetal pulses by finding the minimum and maximum amplitude of each pulse. Once two minimums are found, the distance between them is measured in time. From this time, the pulse rate in beats per minute (bpm) is calculated. The optical pulse rate is displayed by the N-400 only when pulse quality is adequate to also calculate and display a fetal oxygen saturation value.

Caution: The *OxiFirst* System's optical pulse rate can be affected by uterine contractions, fetal perfusion, arrhythmias, and sensor placement, and therefore **should not be used in place of fetal heart rate.**

Unpacking and Inspection

If the shipping carton is damaged, immediately notify the carrier.

Carefully unpack the N-400 and accessories. Confirm that all components are enclosed, and inspect each one. If any are missing or damaged, contact Nellcor's Technical Service Department or your local Nellcor representative.

List of Components

- N-400 Fetal Pulse Oximeter (with quick reference pull-out cards)
- N-400 Fetal Patient Module
- AC power cord
- *N-400 Fetal Pulse Oximeter Operator's Manual*
- *Information for Prescribers*
- *Clinical Use Guide*

Typical Setup

Figure 6 shows a typical *OxiFirst* System setup. The N-400 processes the optical signal seen by the fetal oximetry sensor, and displays calculated $FSpO_2$ and pulse rate values derived from this signal. The N-400 is typically interfaced to an electronic fetal heart rate monitor (EFM) via either a digital or analog connection, and the $FSpO_2$ signals are recorded on the EFM strip chart.

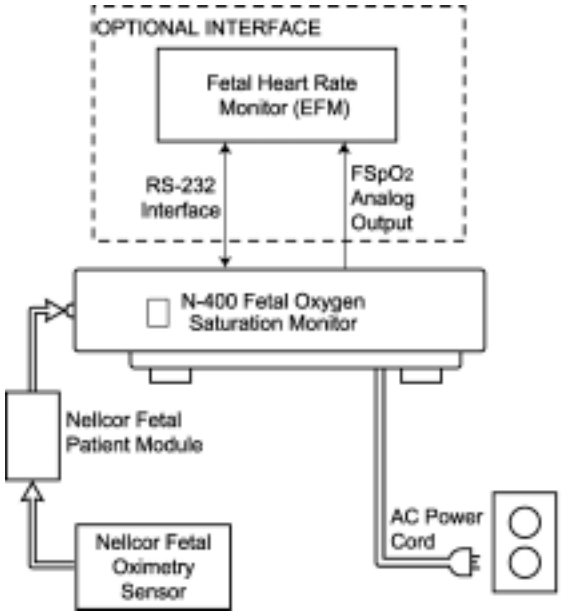


Figure 6: Typical *OxiFirst* System Setup

Setting up the N-400

1. Ensure that the mains (AC) voltage selector on the back of the N-400 has been set for the appropriate mains (AC) voltage.

2. Connect the mains (AC) power cord to the N-400. Plug the other end of the cord into a hospital-grade outlet.

   Use only an outlet that has a grounding connection and use only the original hospital-grade mains (AC) power plug and cord, or an equivalent hospital-grade mains (AC) power plug and cord.

3. Verify that the front-panel ON/STANDBY switch is in the STANDBY position.

4. On the N-400 rear panel, turn the mains (AC) ON/OFF switch to ON.

C/O

5. On the N-400 front panel, turn the ON/STANDBY switch to ON.

   Note: Steps 4 and 5 above must be completed in the order indicated.

Power Up and Self-test

Each time the ON/STANDBY switch is turned ON, the N-400 performs a self-test. If a problem is detected during the self-test, an error code will be displayed. Refer to the *Troubleshooting Guide* section in this manual for information regarding error codes.

After setting up the N-400, and each time the monitor is turned on, verify the following during the N-400 power up sequence:

- All the display icons are lit and then extinguished. The speaker sounds.
- The software version is briefly displayed in the $FSpO_2$ and pulse rate display fields.
- The display is initialized with dashes in the $FSpO_2$ and pulse rate display fields.
- The Audio Alarm Off indicator is on.
- The Sensor Lifted indicator is on if the sensor is plugged in; if not, the Sensor Unplugged indicator will be on.
- The Signal Quality indicator has a single bar lit at the far left.
- The Pulse Amplitude indicator has one or two segments lit if the sensor is plugged in; if not, the Pulse Amplitude indicator has only the bottom bar illuminated.
- All other indicators are off.

Note: The $FSpO_2$ analog output should remain at zero volts throughout the power-up sequence.

If the behavior is not as described, contact Nellcor's Technical Service Department (1.800.NELLCOR) or your local Nellcor representative.

Carefully read this manual, the *Information for Prescribers*, the *Clinical Use Guide*, accessory directions for use, and all warnings, precautions, and specifications before application and use of the *OxiFirst* System.

Basic Operation

The following procedure outlines the N-400 default mode of operation.

To turn the N-400 ON:

1. Ensure that the mains (AC) voltage selector on the back of the N-400 has been set for the appropriate mains (AC) voltage.

2. Connect the mains (AC) power cord to the N-400. Plug the other end of the cord into a hospital-grade outlet. Use only an outlet that has a grounding connection and use only the original hospital-grade mains (AC) power plug and cord, or an equivalent hospital-grade mains (AC) power plug and cord.

3. Verify that the front panel ON/STANDBY switch is in the STANDBY position.

4. On the N-400 rear panel, turn the mains (AC) ON/OFF switch to ON.

5. On the N-400 front panel, turn the ON/STANDBY switch to ON.

   Note: Steps 4 and 5 above must be completed in the order indicated.

6. Connect the fetal patient module to the N-400 front panel Patient Module connector. Align the red dots on the connector and the front panel. Push the patient module connector straight in. Do not twist the connector.

7. If desired, set the N-400 low saturation alarm limit (see *Alarms* in this section). The default low saturation alarm limit is zero.

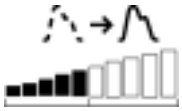
8. If desired, set the response mode.

9. Plug the fetal oximetry sensor into the sensor connector on the fetal patient module. The Sensor Unplugged indicator light should turn off and the Sensor Lifted indicator should turn on.

10. Place the sensor as described in the *Sensor Quick Guide* or *Flowchart Pull-out Card* and the *Clinical Use Guide*.

11. After the sensor is appropriately positioned, the Sensor Lifted indicator turns off and the Searching indicator turns on.

12. The Pulse Amplitude indicator lights up with each pulse, with the number of bars lit dependent upon pulse strength.



13. The Signal Quality indicator lights up to display the quality of the signal used to calculate the FSpO2 value.

14. When the signal quality is maintained above six segments, FSpO2 and fetal pulse rate values will typically be displayed within 10 to 30 seconds.

15. The volume of the pulse tone can be adjusted by turning the control knob.

16. To acknowledge an alarm, press the audio alarm off button. Press the button again to reactivate audible alarms, if desired.

Alarms

The default mode for audible alarms is OFF.

If the operator enables an audible alarm, the N-400 generates both an audible and a visible alarm to alert the user to a low saturation condition; an audible alarm alerts the user to lost signal conditions. The audible alarm has a set default volume, which may be adjusted as required. The alarm pitch, however, is fixed. The displayed FSpO2 value also rapidly flashes as a visible low saturation alarm indicator.

Front panel push buttons and the control knob are used to set the low saturation alarm limit, enable the audio alarm, and adjust the alarm volume. These features reset to their default states whenever the ON/STANDBY switch is turned to STANDBY or the mains (AC) ON/OFF switch is turned to OFF.

Enabling Audio Alarm

The default mode for the audio alarm is OFF.

To enable the Audio Alarm:

1. Press the Audio Alarm Off button.
2. The Audio Alarm Off indicator is no longer displayed.
3. Audio alarms are now enabled.

Disabling Audio Alarms

To disable the Audio Alarm:

1. Press the Audio Alarm Off button.
2. The Audio Alarm Off indicator lights steadily.
3. The audio alarm is now disabled (OFF).

4. Pressing the Audio Alarm Off button again can reactivate the audio alarm.

Silencing the Audio Alarm

Pressing the Audio Alarm Off button when an alarm sounds inhibits the alarm. The Audio Alarm Off indicator lights steadily to show that the audio alarm has been silenced.

Adjusting Audio Alarm Volume

When the audio alarm is enabled, the default state for the audio alarm volume is about 40% of maximum. When the operator turns the N-400 off, then back on again, the audio alarm returns to this default volume.

Note: To adjust the audio alarm volume, the operator must press two front panel buttons simultaneously. If both buttons are not pressed simultaneously, the audio alarm off state may be toggled. After adjusting the audio alarm volume, check to ensure that the desired state for audio alarm off is selected.

To adjust audio alarm volume:

1. Simultaneously press and hold both the Low Saturation Limit and the Audio Alarm Off buttons.

2. Turn the control knob clockwise to increase the volume or counter-clockwise to decrease the volume.

3. When the desired volume has been selected, release the buttons.

Caution: If audio alarms are enabled, do not set the alarm volume too low to be heard, or disable an audible alarm without correcting the alarm condition. Doing so may compromise patient safety.

Low Saturation Limit Alarm

For a low saturation limit alarm condition, both the visible and audible alarm states are active until:

- The saturation becomes greater than, or equal to, the specified limit.
- The saturation alarm limit is readjusted to less than the currently displayed saturation.

Audible Alarms and Visible Indicators for Lost Signal

An audible alarm state for a lost signal is generated after 15 seconds of the following conditions:

- The FSpO2 signal from the fetal oximetry sensor is lost.
- The sensor is lifted.
- The signal quality remains below an accepted level.

An audible alarm is immediately generated when:

- The fetal oximetry sensor is unplugged from the Fetal Patient Module.
- The Fetal Patient Module is unplugged from the N-400.

Note: For an audible alarm state to be generated in any of the above conditions, the N-400 must be posting (that is, displaying on the monitor front panel) FSpO2 and pulse rate values.

Visible indicators help direct the operator to probable causes of lost signal conditions. An overview of the lost signal conditions is shown in Table 1 on page 32.

Table 1: Lost Signal Conditions

Condition	Visible Alarm or Advisory	Audible Alarm [a]
Sensor Unplugged [b]		Alarm sounds
Searching for fetal pulse [b]		Alarm sounds
Signal Quality remains below threshold [b]		Alarm sounds
Sensor Lifted: Sensor in air or possibly in vagina [b]		Alarm sounds
Sensor lifted: Sensor may be floating in amniotic fluid and is not in contact with fetal skin	and	Alarm sounds
Sensor lifted: Sensor may be covered with vernix	*and flashing*	Alarm sounds
Sensor may be over hair or other light-absorbing surface		Alarm sounds
Sustained poor signal quality	*and*	Alarm sounds

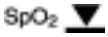
a. The default mode for the audible alarms is OFF. The alarm mode must be enabled for alarms to sound.
If the monitor has been displaying FSpO2 values prior to an alarm condition, the alarm will sound when the FSpO2 values are removed from the display.

b. During this condition, both FSpO2 and pulse rate fields display dashes.

Setting Low Saturation Alarm Limit

The default value for the low saturation alarm limit is zero (0).

To set the low saturation alarm limit:



1. Press and hold the Low Saturation Limit button. The current limit is displayed in the FSpO2 display. The pulse rate display is blank.

2. Turn the control knob clockwise to increase the value or counter-clockwise to decrease the value. The limit range is 0 to 100, with 0 disabling the low saturation alarm.

3. After selecting the desired value, release the Low Saturation Limit button.

Setting Pulse Tone Volume

The Pulse Tone volume is set to a default level at power-up. If pulse tones are not loud enough, rotate the control knob on the N-400 front panel clockwise to increase the audible volume.

When FSpO2 values are being displayed, each accepted pulse produces a beep tone that varies in pitch, reflecting changes in fetal oxygen saturation. The pitch increases as saturation increases and decreases as saturation decreases. Refer to the *Clinical Use Guide* for detailed instructions on the use of the pulse tone during sensor placement and adjustment.

When FSpO2 values are **not** displayed, each accepted pulse produces a low-pitched beep (pulse tone). When the sensor is well positioned, these beeps sound in a rhythmic pattern matching the fetal heart rate.

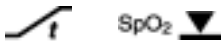
If the beeps are intermittent or irregular, a slight adjustment may optimize the sensor placement, producing more continuous FSpO2 readings and improved monitoring quality.

After using this feature to assist in optimizing sensor placement, the Pulse Tone volume may be lowered or silenced by rotating the control knob counter-clockwise.

Setting Date/ Time

Setting the date and time updates the N-400 internal clock to the new values. The time is recorded on serial communication printouts when the N-400 is used in conjunction with serial communication devices.

To set the date and time:



1. Press the Response time (RT) and the Low Saturation Limit (LS) buttons simultaneously.

   Note: Setting the date and time requires the operator to press two front panel buttons simultaneously. If both buttons are not pressed simultaneously, Response Time may be toggled. After setting date and time, check to ensure that the desired response time is selected.

2. Release the Low Saturation Limit button while continuing to press the Response Time button until the display or edit of the date and time is completed.

3. The date and time parameters are displayed in the following sequence: year, month, day, hour, and minute.

	Saturation Display	Rate Display
The first press of the RT and LS buttons:	Year (blinking)	
Holding the RT button and again pressing the LS button:	Month (blinking)	Day
Holding the RT button and again pressing the LS button:	Month	Day (blinking)
Holding the RT button and again pressing the LS button:	Hour (blinking)	MINUTE
Holding the RT button and again pressing the LS button:	Hour	Minute (blinking)

4. To edit the blinking parameter, turn the control knob clockwise to increase or counter-clockwise to decrease the number. The range to which any particular parameter can be edited is dependent upon the year, leap year, or non-leap year, and the month.

5. Holding the RT button and again pressing the LS button will continue the cycle from the top, allowing continued display or editing.

6. Release both buttons at any time to discontinue the display and edit of the time parameters.

   Note: After releasing both buttons, allow the display to return to the normal display mode—approximately three seconds—before pressing another button or turning the control knob. This elapse of three seconds is necessary to ensure the instrument successfully stores the date and time revisions in instrument memory.

Connecting Digital Instruments

The information required to support the N-400 RS-232 serial communications port is provided in this section.

Caution: Turn the N-400 rear panel AC mains switch OFF prior to setting the DIP switches and connecting another device to the N-400 monitor.

Serial Data Connector Pin Assignments

Table 2 lists pin assignments on the N-400 rear panel RS-232 serial communications port (a 9-pin "D" connector) and the corresponding pin assignments for a 25-pin RS-232 connector of an external device.

Table 2: Serial Data Connector Pin Assignments

N-400 Connector Pin	Signal	Direction	External Device Signal	External Device Pin
1	not used	none	none	none
2	Rx data	←	Tx data	2
3	Tx data	→	Rx data	3
4	not used	none	none	none
5	Signal Ground	↔	Signal Ground	7
6	not used	none	none	none
7	not used	none	none	none
8	CTS	←	RTS	4
9	not used	none	none	none

Note: Pin 8 (CTS) may be used to control transmission data. When held "high" (positive voltage), the data transmission takes place. When held "low" (negative voltage), the data transmission is suspended temporarily.

Caution: Loss of data may occur if pin 8 is held in a LOW logic state for longer than four seconds.

Setting Baud Rate

The rear panel RS-232 format switches are used to set the N-400 baud rate and the communications port format.

Identify the baud rate required by the device that is to be connected, and set the N-400 baud rate using the rear panel baud rate switches. Refer to Table 3.

Note: In order for the new DIP switch settings to be recognized, the rear panel AC mains switch must be turned off and then on again.

Table 3: Baud Rate DIP Switch Settings

	Switch Selections	
Baud Rate	**3**	**4**
1200	up	up
2400	down	up
9600	up	down
19200	down	down

Communication Formats

The rear panel RS-232 format switches used to set the communication port format are shown in Table 4. The serial communication format of the N-400 is eight data bits, no parity bit, and one stop bit. No other communication formats are supported.

Note: In order for the new DIP switch settings to be recognized, the rear panel AC mains switch must be turned off and then on again.

Table 4: Communication Format DIP Switch Settings

		Switch Selections		
Format Name	**Description**	**6**	**7**	**8**
Beat-to-Beat	Outputs rate and saturation once per accepted pulse	DOWN	UP	DOWN
Conversation	Request for parameter	DOWN	DOWN	UP
Conversation and Beat-to-Beat	Combination of the above two formats	DOWN	UP	UP

Beat-to-Beat Format

This mode transmits fetal saturation and pulse rate data once per beat in the following format:

RnnnSnnn<SPACE><CR><LF>

where:

R = Fetal Pulse Rate
S = Saturation FSpO2%
<SPACE> = 20 hex
<CR> = 0D hex
<LF> = 0A hex

Conversation Format

In this mode, the output is a single parameter that is sent by request only. For example, the external device requests the current pulse rate by sending an R. The N-400 responds with:

<STX>Rnnn<CR><LF>

where:

R = Fetal Pulse Rate
<STX> = 02 hex
<CR> = 0D hex
<LF> = 0A hex

The supported request codes are:

R = Fetal Pulse

P = Signal Quality (updated on a beat-to-beat basis)

O = Low Saturation Alarm Limit Value

A =Alarm Status in ASCII-coded decimal:

Bit 0, 1, 3 = not used (default = 0)

Bit 2 = Low Saturation Alarm (1 = alarm active, 0 = no alarm)

Bit 4, 5, 6, 7 = not used

For example, ASCII 004 = binary 0100 = Low Saturation Alarm Limit active.

M =Monitor Status in ASCII-coded decimal:

Bit 0 = Pulse Search Status	1 = Saturation displayed	0 = Saturation not displayed
Bit 1 = Sensor Status	1 = Attached	0 = Unplugged or Invalid Sensor
Bit 2 = Audio Alarm Status	1 = Enabled	0 = Disabled
Bit 3 = not used (default = 1)		
Bit 4 = Response Time	1 = Mode 2	0 = Mode 1
Bit 5 = Sensor Contact	1 = Sensor In Contact	0 = Sensor Lifted
Bit 6 = For engineering use only (default = 1)		
Bit 7 = Monitor Communication	1 = Lost	0 = Intact

For example, if the monitor status byte is ASCII 111 (binary 01101111), this means that the monitor is reporting FSpO2 readings, a sensor is attached, audio alarms are enabled, mode 2 is selected, and the sensor is in contact.

T = Time hhmmss

V = Nellcor N-400 software versions:

Nellcor N-400 4.n.n.nn<SPACE>[4.n.n.nn]

where:

4.n.n.nn = oximetry software version

[4.n.n.nn] = communications software version

Analog Instruments

The information required to connect an analog instrument to the N-400 is provided in this section.

Caution: Turn the N-400 rear panel AC mains switch OFF before connecting another device to the N-400 monitor.

Connecting an Analog Device

A general-purpose strip-chart recorder or an EFM with analog input capability may be connected to the N-400 to provide a permanent record of fetal oxygen saturation.

Note: Connect only a high impedance device (100k ohms or higher) to the analog output connector. Improper loading distorts the correspondence between the measured voltage and the intended output voltage.

The N-400 FSpO2 analog output connector is a standard 3/32-inch subminiature phone plug. The output voltage range (0–1 V or 0–10 V) required by the recorder or EFM is set with a DIP switch on the N-400 rear panel. DIP switch 1 is set DOWN for 0–1 volt scaling or UP for 0–10 volt scaling.

Note: In order for the new DIP switch settings to be recognized, the rear panel AC mains switch must be turned off and then on again.

Use the Decrease (zero) and Increase (full-scale) buttons on the N-400 rear panel to generate zero and full-scale voltage signals in order to adjust the recorder controls.

Maintenance

Caution: Do not attempt to remove the outside monitor cover. Doing so may result in electrical shock hazard. There are no user-serviceable parts inside.

Service

The N-400 requires no routine service other than that mandated by the operator's institution. A brief troubleshooting guide in the next section of this manual discusses potential problems, possible causes, and recommended resolutions. Complete service instructions, including preventive maintenance checks, are contained in the *N-400 Service Manual*, available from Nellcor's Customer Service Department.

Maintenance

Performance and safety checks are recommended once every two years, as described in the *N-400 Service Manual.*

Cleaning

Caution: Do not immerse the N-400 in liquid or use caustic or abrasive cleaners.

To clean the surface of the N-400, dampen a cloth with a commercial, nonabrasive cleaner, and wipe all monitor surfaces lightly. Do not spray or pour any liquid directly on the N-400 or its accessories. Do not allow any liquid to come in contact with the power connector, fuse holder, or switches. Do not allow any liquids to penetrate connectors or openings in the chassis.

Technical Assistance

For technical information and assistance, contact Nellcor's Technical Service Department (1.800.NELLCOR) or your local Nellcor representative. To order parts or a service manual, contact Nellcor's Customer Service. The service manual includes circuit diagrams and a parts list required by qualified personnel when servicing the N-400.

Returning the N-400

Before returning the N-400 to Nellcor, call Nellcor's Technical Service Department for shipping instructions and Returned Goods Authorization (RGA).

If possible, return the N-400 in its original shipping carton. Otherwise, use a sturdy box. Wrap the N-400 and the patient module separately. Do not return the sensor. Place the wrapped units in the box and pad with an appropriate amount of packing material. Seal the box with strapping tape.

Note: Several of the indicators and messages described within this chapter are specific to the N-400 monitor. Electronic fetal heart rate monitors using Nellcor FSpO2 technology may function differently than the N-400. Refer to manufacturer's documentation for details.

Status Messages

Table 5 lists status messages along with actions to clear error messages. If the recommended actions do not clear the error, contact Nellcor's Technical Service Department or your local Nellcor representative.

Note: Errors are indicated with Err in the FSpO2 display and the error code number in the pulse rate display.

Caution: Do not continue to use the N-400 monitor if error messages are not corrected by the recommended action.

Note: Those error messages marked with an asterisk (*) in Table 5 will be cleared if any front panel button is pushed. The N-400 can then be used for monitoring. However, contact Nellcor's Technical Service Department or your local Nellcor representative as soon as possible to determine the root cause of the problem associated with that particular error message.

Table 5: Status Messages

Code	Cause	Solution
Err 1	Defective data memory, or the N-400 line voltage selected is not the same as the mains (AC) supply voltage.	Contact Nellcor's Technical Service Department or your local Nellcor representative, or change the line voltage selection on the N-400 rear panel to match the mains (AC) line voltage.

Table 5: Status Messages (Continued)

Code	Cause	Solution
Err 2	Defective program memory.	Contact Nellcor's Technical Service Department or your local Nellcor representative.
Err 3*	Defective display segment or indicator, or possibly a circuit malfunction.	Contact Nellcor's Technical Service Department or your local Nellcor representative. Note: An Err 3 may be cleared by pressing any front panel button. However, if any numeric display segment or indicator is missing, the display or indicators may be incorrect.
	Caution: Continue to use the N-400 only in an urgent situation and only if the defective display segment(s) or indicator has been identified. If a defective segment cannot be identified, do not continue to use the N-400.	
Err 4*	Clock battery failure.	Contact Nellcor's Technical Service Department or your local Nellcor representative.
Err 5*	Communication failure.	Contact Nellcor's Technical Service Department or your local Nellcor representative.
Err 6*	Clock battery failure.	Contact Nellcor's Technical Service Department or your local Nellcor representative.
Err 7	A front panel button is stuck or held in position during monitor power-on self-test.	Check all front panel buttons for proper operation. Do not hold buttons while powering up the monitor. If unable to resolve the problem, contactNellcor's Technical Service Department or your local Nellcor representative.

Table 5: Status Messages (Continued)

Code	Cause	Solution
Err 8	The N-400 line voltage selected is not the same as the mains (AC) supply voltage.	Change the line voltage selection on the N-400 rear panel to match the mains (AC) line voltage.
Err 9	Memory failure.	Contact Nellcor's Technical Service Department or your local Nellcor representative.
Err 10	Memory failure.	Contact Nellcor's Technical Service Department or your local Nellcor representative.
Err 119	Memory failure.	Turn the On/Standby switch to Standby and the mains (AC) ON/OFF switch to Off. After approximately five seconds, set the mains (AC) switch back to ON and the On/Standby switch back to on. If this does not solve the problem, contact Nellcor's Technical Service Department or your local Nellcor representative.
Err 120	Memory Failure.	Turn the On/Standby switch to Standby and the mains (AC) ON/OFF switch to Off. After approximately 5 seconds, set the mains (AC) switch back to ON and the On/Standby switch back to on. If this does not solve the problem, contact Nellcor's Technical Service Department or your local Nellcor representative.
Err 121*	Clock failure.	Contact Nellcor's Technical Service Department or your local Nellcor representative.

Table 5: Status Messages (Continued)

Code	Cause	Solution
Err Pb*	Internal communications problem.	Turn the On/Standby switch to Standby and the mains (AC) ON/OFF switch to Off. After approximately 5 seconds, set the mains (AC) switch back to ON and the On/Standby switch back to on. If this does not solve the problem, contact Nellcor's Technical Service Department or your local Nellcor representative. Note: The N-400 will clear the **Err Pb** message if the communication problem clears itself or, if any front panel button is pushed while **Err Pb** is displayed; however, rear panel buttons and connectors may not operate, and data communications may not occur.
Err Sen	Sensor is not compatible with the system configuration.	Replace sensor with a compatible sensor.

Note: If an error message is displayed that is not listed in Table 5, turn the ON/STANDBY switch to STANDBY and the mains (AC) ON/OFF switch to OFF. After approximately five seconds, set the mains (AC) switch back to ON and the ON/STANDBY switch back to ON. This may temporarily solve the problem. However, contact Nellcor's Technical Service Department or your local Nellcor representative as soon as possible to determine the root cause of the problem associated with the error message.

Trouble-shooting Guide

This section discusses potential problems and suggestions for resolving them. The *N-400 Service Manual*, intended for use by qualified service personnel, provides additional troubleshooting information.

Refer to the *Sensor Quick Guide* and the *OxiFirst System Clinical Use Guide* for complete instructions on sensor use, and troubleshooting information regarding sensor placement and adjustment. If the difficulty persists, contact Nellcor's Technical Service Department or your local Nellcor representative.

Potential Problems and Resolutions

1. Displayed FSpO2 does not correlate with the SaO2 value calculated from a fetal scalp blood sample measurement on a blood gas analyzer.

   - Close correlation requires simultaneous blood sampling and pulse oximeter measurements from the same arterial supply. Blood samples exposed to air during the sampling process may not accurately reflect true arterial values.
   - The SaO2 calculation may not have been correctly adjusted for the effects of pH, temperature, PaCO2, 2,3-DPG, or the presence of fetal hemoglobin. Check whether calculations have been corrected appropriately for relevant variables. (See the *Principles of Operation* section in this manual for more information.) In general, calculated SaO2 values are not as reliable as direct CO-oximeter or pulse oximeter measurements.
   - *OxiFirst* System accuracy can be affected by incorrect sensor application or use, significant levels of dysfunctional hemoglobins, excessive patient movement, venous pulsation, or nearby electrosurgical interference. Observe all instructions, warnings, and cautions in this manual and in the *OxiFirst System Clinical Use Guide*.
   - Oxygen saturation greater than 85% and/or pulse rate less than 100 bpm could indicate that the values are maternal in origin. Check sensor placement to ensure that it is properly positioned on the fetus.

2. Displayed $FSpO_2$ does not correlate with the SaO_2 value calculated from a fetal scalp blood sample measurement on a laboratory CO-oximeter.

   - Close correlation requires simultaneous blood sampling and pulse oximeter measurements from the same *arterial* supply. Blood samples exposed to air during the sampling process may not accurately reflect true arterial values.
   - Fractional measurements may not have been converted to functional measurements before the comparison was made. The N-400, as well as other two-wavelength oximeters, measures functional saturation. Multi-wavelength oximeters measure fractional saturation. Fractional measurements must be converted to functional measurements for comparison. Refer to the equation for this conversion in the *Principles of Operation* section in this manual.
   - Oxygen saturation greater than 85% and/or pulse rate less than 100 bpm could indicate that the values are maternal in origin. Check sensor placement to ensure that it is properly positioned on the fetus.
   - Check whether or not CO-oximeter values have been correctly adjusted for the presence of fetal hemoglobin.

3. Displayed pulse rate does not agree with that of an electronic fetal heart rate monitor.

   - Excessive maternal or fetal patient motion may be making it impossible for the N-400 to find a pulse pattern. If possible, keep the mother still.
   - Check fetal heart rate by auscultation.
   - Ensure that the sensor is properly positioned on the fetus.
   - Oxygen saturation greater than 85% and/or pulse rate less than 100 bpm could indicate that the values are maternal in origin. Check sensor placement to ensure that it is properly positioned on the fetus.

4. FSpO2 saturation > 85%.

    - The sensor may be facing the uterine wall and may be reading maternal saturation. Confirm that the sensor is positioned correctly against the fetus.
    - The sensor has white markings on both sides. The side with numbers at 1 cm intervals (30, 29, 28, 27…) should be facing toward the fetus. The side with numbers only at 17, 20, 25, 30 is the maternal side and should be facing away from the fetus.
    - Palpate the maternal pulse and compare it to the heart rate displayed on the fetal heart rate monitor and to the pulse rate displayed on the N-400 monitor. If the maternal pulse matches the N-400 displayed pulse rate, sensor is most likely monitoring maternal oxygen saturation. Reposition or adjust the sensor.
    - Normal sensor operation may be affected by maternal pulsations or vernix in the fluid channel. Withdraw the sensor in 1 cm increments to better position the sensor; hold in place for 15 seconds.
    - If still unsuccessful in correcting this condition, completely withdraw sensor and inspect for vernix in the fluid channel.

5. N-400 does not turn on.

    - Check that the mains (AC) ON/OFF switch on the rear panel is set to ON. (Mains (AC) must be switched on **before** the standby switch on the front panel is turned on.)
    - Check mains (AC) connection. Check that the N-400 is connected properly to mains (AC) supply.
    - Check that the AC voltage selector is set for the correct voltage range.
    - Check mains (AC) fuses.

6. Fetal Patient Module cannot be connected to the monitor.

   - Use only a Nellcor Fetal Patient Module.
   - Connector pins may be bent; replace with another Fetal Patient Module.

7. Sensor Unplugged indicator is on or the red sensor emitter is not lit.

   - Check connection between the sensor and the patient module.
   - Check connection between patient module cable and front panel of monitor.
   - If all connections are okay, try a new sensor.
   - If problem persists, try a new Fetal Patient Module.
   - If problem persists, contact Nellcor's Technical Service Department or your local Nellcor representative.

8. Fetal heart rate slows during, or immediately following, sensor placement.

   - A fetal response to stimulation could cause a reflex bradycardia.

Caution: If the fetal heart rate slows during vaginal exam or sensor insertion, stop the procedure. Do not proceed with sensor placement as this can cause a reflex bradycardia stimulus. Wait for the fetal heart rate to return to the previous range before proceeding.

9. $FSpO_2$ or pulse rate change rapidly; Pulse Amplitude indicator is erratic.

   - Assess fetal status.
   - Excessive maternal or fetal patient motion may be making it impossible for the N-400 to find a pulse pattern. If possible, keep the mother still.
   - Check whether the sensor is positioned properly on the fetus, and reposition it if necessary.
   - Set the N-400 response time for Mode 1.
   - A nearby electrosurgical unit (ESU) may be interfering with performance.

WARNING: The *OxiFirst* System should not be used while using an Electrosurgical Unit (ESU). Remove the fetal oximetry sensor from the mother and fetus before using an ESU. An improperly grounded ESU can cause surface skin burns on the fetus if both the *OxiFirst* System and an ESU are used together.

Performance

Display Ranges

Pulse Rate	0 to 250 beats/minute
FSpO2	0 - 100%

Accuracy

Pulse Rate	40 to 219 beats/minute, ±3 bpm

FSpO2 Calibration and Reproducibility

Calibration of the *OxiFirst* System was accomplished through controlled hypoxia studies in a piglet model. The calibration was validated in an independent animal study of a different group of piglets and in a multi-center human study comparing N-400 readings to simultaneous laboratory arterial blood saturation values obtained on severely cyanotic human infants and children.

Reproducibility of the system was evaluated under conditions of actual use in a series of dual sensor studies, in which two sensors were placed simultaneously on a human fetus during active labor.

The resulting reproducibility was 1 SD = 4.7%. Nominally, 67% of the measurements across the population will be within ±1 SD (standard deviation).

For a more detailed discussion of accuracy, refer to the Nellcor Perinatal Reference Note #1.[1]

1. Nellcor Perinatal Reference Note #1 (00032-0500): *OxiFirst* Fetal Oxygen Saturation Monitoring System—The Technology

Sensor

Type	Nellcor® Fetal Oximetry Sensor (reflectance sensor)
Heating	Sensor power dissipation is less than 80 mW total heat dissipation by LED's. (Less than 3.0°C temperature rise.)

Controls

Front Panel

ON/STANDBY switch, control knob, audio alarm off button, low saturation limit button, response time button

Rear Panel

Mains (AC) ON/OFF switch, Decrease (zero) button, Increase (full-scale) button, DIP switches (used to set analog output scale, RS-232 format and baud rate)

Alarms

The audible alarm default state is OFF. Audible and visible alarms for low oxygen saturation; audible alarm and visual indicators for loss-of-pulse. The alarm volume and low saturation limit are adjustable. See *Alarms* in the *Guide to Operation* section.

Pulse Tone

Default volume of the audible Pulse tone is On. If enabled, and a signal from the sensor is present, an audible beep sounds with each detected pulse; volume is adjustable with the control knob; pitch varies to reflect changes in oxygen saturation while a saturation is displayed.

Response Modes

Two response modes, selected by the response time button:

- Mode 1 (default), slow, 50 seconds
- Mode 2, fast, 11 seconds (at 150 bpm)

Switches

Ten for digital output format and analog output voltage range.

Switch Selection	Function
1	analog output voltage range
2, 5, 9, 10	not used
3, 4	Baud rate selection
6, 7, 8	RS-232 format

Data I/O

Digital

Type	RS-232 format
Connector	9-pin D-type, female
Baud Rate	Switch-selectable, 1200, 2400, 9600, and 19200
Formats	Conversation, beat-to-beat

Analog

Type	3/32-inch subminiature phone jack (3; 2 unused)
Outputs	FSpO2
Voltage	0-1 or 0-10 V (switch-selectable, DIP switch 1)
Maximum voltage output:	10 V
Accuracy	±20 mV at zero (0), ±0.5% of full scale, referred to front panel display

Note: An analog output of zero volts indicates that either the reported FSpO2 value is zero or the FSpO2 is not being reported.

Connectors

Front Panel

Fetal Patient Module Connector

Rear Panel

FSpO2 analog output jack (3/32-inch)

Serial communications connector (9-pin, D-type connector)

Mains (AC) power input

Electrical

Voltage Requirement	100-120 V ± 10% AC at 50/60 Hz
Current Requirement	300 mA maximum
Power Consumption	Maximum rating: 30 VA
Fuses	115V~ 2 x T 500 mA, 250 V~

Classification

Protective Class	Class I
Degree of Protection	Type BF
Enclosure: Degree of Protection	Ordinary (IPXO)
Mode of Operation	Continuous

Physical

Monitor

Dimensions	12.6 inches x 12 inches x 3.5 inches (W x D x H) (32 cm x 30 cm x 8 cm)
Weight	9 lbs (4.1 kg)

Patient Module

Cable length	13 ft (4 m) cable
Connectors	Lemo B-series, mates with 12-pin connector on N-400 front panel; fetal sensor connector, mates with 9-pin connector on the fetal oximetry sensor

Environmental Conditions

Transport (in shipping container)

Temperature	-40°C to +70°C (-40°F to +158°F)
Altitude/ Barometric Pressure	-390 m to +6,096 m (-1280 ft to +20,000 ft) +1060 hPa to +500 hPa (+31.1 in. Hg to +14 in. Hg)
Relative Humidity	15% relative humidity to 95% relative humidity (non-condensing)

Storage (not in shipping container)

Temperature	-20°C to +60°C (-4°F to +140°F)
Altitude/ Barometric Pressure	-390 m to +6,096 m (-1280 ft to +20,000 ft) +1060 hPa to +500 hPa (+31.1 in. Hg to +14 in. Hg)
Relative Humidity	15% relative humidity to 95% relative humidity (non-condensing)

Operating

Temperature	+5°C to +40°C (+41°F to +104°F)
Altitude/ Barometric Pressure	-390 m to +6,096 m (-1280 ft to +20,000 ft) +1060 hPa to +500 hPa (+31.1 in. Hg to +14 in. Hg)
Relative Humidity	15% relative humidity to 95% relative humidity (non-condensing)

Emissions Compliance

EN55011 Emissions Classification

CISPR II, Group I, Class B

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